DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Orpheus Medical, Ltd.
% Clay Anselmo
President
Reglera, LLC
11925 West I-70 Frontage Road, Suite 900
Wheat Ridge, CO 80033

JUL 27 2015

Re: K132426
Trade/Device Name: Medic VOD System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated (Date on orig SE ltr): January 25, 2013
Received (Date on orig SE ltr): January 31, 2013

Dear Clay Anselmo,

This letter corrects our substantially equivalent letter of March 1, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123426

Device Name: MedicVOD System

Indications for Use:

The MedicVOD System is a picture archival and communications systems (PACS) that is intended for image capturing, archiving, displaying and recording of audio/video sequences and patient data during a procedure. The system allows for capture and annotation of the surgical procedure for documentation purposes and for viewing at a later time either locally or on a secure distributed network. The captured audio/video sequences can be broadcasted in realtime with video-conferencing capability during the broadcast. Information captured and stored by the system are for viewing and reference purposes only and are not intended for primary diagnosis.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ____K123426____

K123426
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510(k) Summary: MedicVOD System

MAR 0 1 2013

1 INTRODUCTION

1.1 This document contains the 510(k) Summary for the MedicVOD system. The content of this document is based on the requirements of 21 CFR 807.92

2 APPLICANT NAME AND ADDRESS

2.1 **Name:** Orpheus Medical Ltd.

2.2 **Address**: 5 Haetgar St. POB 15140, MATAM Industrial Zone HAIFA 31905, Israel

2.3 **Official Contact**: David Rainis, CEO

2.4 **Summary Preparation Date**: October 29, 2012

3 DEVICE NAME AND CLASSIFICATION

3.1 **Name of Device:** MedicVOD System

3.2 **Common Name:** Picture Archiving and Communication System

3.3 **Classification Name:** Picture Archiving and Communication System

3.4 **Classification:** II

3.5 **Classification Panel**: Radiology

3.6 **Regulation Number**: 21 CFR 892.2050, 21 CFR 876.1500

3.7 **Product Code**: LLZ, KOG

4 PREDICATE DEVICE:

4.1 AIDA with DICOM and HL7 interface, by Storz, cleared under K043324

4.2 660 HD Image Management System, by Smith & Nephew, cleared under K060777

4.3 SwitchPoint Infinity®3 (SPI3) Control System, by Stryker Communications, cleared under K100852

5 DEVICE DESCRIPTION:

5.1 The MedicVOD System is a video system enabling medical teams to document, record and broadcast live medical procedures in real time. Its four components are:

5.1.1 The mediCAST station, attached to the imaging device in an operating theater

5.1.2 The mediShow application, a real-time monitoring application, displaying sessions from all currently active mediCAST stations

5.1.3 The mediSearch video archive search and edit application

5.1.4 The MedicVOD Server which is a central storage system (CSS) for archival of all mediCAST sessions

5.2 The MedicVOD key features include:

5.2.1 Digital recording of medical procedures streamed directly to on-site server for storage and retrieval,

5.2.2 Live broadcast of a medical procedure to an unlimited number of viewers,

5.2.3 Archiving of video assets to a controlled storage resource,

5.2.4 Data fetching with dynamic categories which may be used by other 3rd party applications for purposes such as statistical analysis of data usage and/or user operation and report production, and

5.2.5 Ability to view/review videos from any mediShow location at any time

5.3 The mediCAST station is capable of capturing and broadcasting a video stream in real time. MediCAST station captures and stores video and still images locally, and in parallel, uploads the capture images and video streams to the MedicVOD server. The mediCAST station uploads the videos and images when there is communication with the MedicVOD server.

5.4 The mediSearch application provides the ability to search within the MedicVOD archive. The mediSearch application allows users to perform searches for video recordings within a captured mediCAST session. Each session could be a combination of several recordings of various kinds. For example, a session could be a combination of several video recordings, several still images (snapshot taken) and several DICOM images that have been stored. MediSearch provides the ability to view the assets which were found, and provides certain editing capabilities.

5.5 The mediShow application automatically connects into the MedicVOD server and displays currently active sessions or procedures captured by any mediCAST station on the local network.

6 INDICATIONS FOR USE:

6.1 The MedicVOD System is a picture archival and communications systems (PACS) that is intended for image capturing, archiving, displaying and recording of audio/video sequences and patient data during a procedure. The system allows for capture and annotation of the surgical procedure for documentation purposes and for viewing at a later time either locally or on a secure distributed network. The captured audio/video sequences can be broadcasted in real-time with video-conferencing capability during the broadcast. Information captured and stored by the system are for viewing and reference purposes only and are not intended for primary diagnosis.

7 INTENDED USE:

7.1 The MedicVOD system is intended as a radiological image processing system that allows for the capture, transfer, display, storage, and digital processing of medical images.

8 PERFORMANCE STANDARDS:

8.1 This 510(k) submission was written in accordance with the FDA guidance document "Guidance for the Submission of Premarket Notifications for Medical Image Management Devices- July 27, 2000", "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005", and "General Principles for Software Validation; January 2002". The design of the MedicVOD System conforms to the following voluntary standards:

8.1.1 Digital Imaging and Communications in Medicine (DICOM): PS 3.3-2004, National Electrical Manufacturers Association.

8.1.2 IEC/EN 60601-1-4:1997, General Requirements for Programmable Electrical Medical System.

8.1.3 IEC 62304:2006, Medical Device Software – Software Lifecycle Processes.

8.1.4 IEC/EN-60601-1: 1988 (2nd ed.), Medical Electrical Equipment; Part 1: General Requirements for Safety. Second edition , including amendments #1(1993), #2(1995) and #3(1996).

8.1.5 IEC/EN 60601-1-2:2001, Medical Electrical Equipment; Part 1-2: Collateral Standard: Electromagnetic Compatibility- Requirements and Tests

8.1.6 ISO 15223-1:2012, Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

9 TEST DATA:

9.1 The MedicVOD System has been subjected to extensive safety and performance testing, and verification / validation before release. Final testing of the MedicVOD System included various performance tests and software validation tests designed to ensure that the device meet all of its functional specifications.

9.2 Tests have been performed to ensure the device complies with industry and safety standards and to demonstrate substantial equivalence to the identified predicate devices. All performance testing showed results consistent with the intended uses and performance specifications of the device.

9.3 The following list and table below summarizes the testing performed on the device;

9.3.1 Hardware Verification / Validation

9.3.1.1 Component First Article Inspection

9.3.1.2 Component Functional Verification

9.3.1.3 Electrical Safety

9.3.1.4 Electromagnetic Compatibility

9.3.2 Software Verification / Validation

9.3.2.1 Software unit test

9.3.2.2 Software verification tests

9.3.2.3 Software validation tests

9.3.3 System Level Performance

9.3.3.1 Integrated System Performance Testing

9.3.3.2 Simulated Use

Verification / Validation Description	*Unit or Configuration Tested*	*Method*	*Acceptance Criteria*	*Results*
Component First Article Inspection	Panel PC unit CSS	Visual inspection, installation of proprietary software and testing using designated test software that tests each component and function	Passing results defined within the test software	Passed all applicable tests

Verification / Validation Description	*Unit or Configuration Tested*	*Method*	*Acceptance Criteria*	*Results*
Component Functional Verification	Panel PC unit CSS	Visual inspection, installation of proprietary software and testing using designated test software that tests each component and function	Passing results defined within the test software	Passed all applicable tests
Electrical safety	Panel PC unit CSS	Applicable tests in a certified lab per IEC 60601-1 Applicable tests in a certified lab per IEC 60950	As required by the applicable standards	Passed all applicable tests
Electromagnetic compatibility	Panel PC unit CSS	Applicable tests in a certified lab per IEC 60601-1-2 Applicable tests in a certified lab per IEC 60950	As required by the applicable standards	Passed all applicable tests
Software unit test	mediCast mediShow mediSearch CSS	Bench verification of unit functionality against its requirements using simulated input signals	Compliance with defined requirements, absence of bugs	Passed all tests
Software verification test	mediCast mediShow mediSearch CSS	Complete bench functional and operational tests derived from the software requirements specifications and additional tests for regression, destructive tests, system debugging, white-box and black box tests	Compliance with defined requirements, absence of bugs	Passed all tests
Software validation test	mediCast mediShow mediSearch CSS	Complete bench functional and operational tests derived from the software requirements specifications	As defined in the software test description (see section 16)	Passed all tests

Verification / Validation Description	*Unit or Configuration Tested*	*Method*	*Acceptance Criteria*	*Results*
Integrated System Performance Testing	MedicVOD integrated system	Functional bench testing using a designated test software that tests each and every system components and function, for each system prior to its release	Passing all defined tests defined by the test protocol and embedded within the test software	Passed all tests
Simulated use	MedicVOD integrated system	Functional testing in a clinical environment by potential user/s	Full functionality and satisfactory usability per a defined user questionnaire	Passed all tests

10 SUBSTANTIAL EQUIVALENCE:

10.1 The intended use of the MedicVOD System is the same as identified predicate devices.

10.2 The operating principles and technological characteristics of the MedicVOD System are the same or substantially equivalent to those of the AIDA System, 660 HD System and also to those of the SPI3 Control System. The algorithms used by the MedicVOD System are similar in principle-of-operation and specifications to the algorithms used by the identified predicate devices.

10.3 The physical and performance specifications of the MedicVOD System are the same or similar to the specifications of the AIDA System, 660 HD System and also to those of the SPI3 Control System.

11 CONCLUSION:

11.1 The MedicVOD System is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.